



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Barrett R. Harvey *et al.*

Serial No.: 10/620,278

Filed: July 15, 2003

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Group Art Unit: 1645

Examiner: Ford, V.

Atty. Dkt. No.: UTSB:715US

DECLARATION OF KARL E. GRISWOLD UNDER 37 C.F.R. § 1.132

Assistant Commissioner for Patents
Washington, D.C. 20231

I, KARL E. GRISWOLD, HEREBY DECLARE AS FOLLOWS:

1. I am a citizen of the United States, and currently reside at 3205-C Grooms Street, Austin, TX, 78705.

2. I have been employed by The University of Texas from 1999 until 2005, with the title of Research Assistant. During that time I was a graduate student at The University of Texas. My primary duties as a Research Assistant were in conducting scientific research in the area of protein engineering. My supervisor was Brent Iverson, Ph.D., who is a co-inventor of the above captioned patent application.

3. I have been conducting research in the area of protein engineering and molecular biology since 1999. I have a Bachelors degree in Chemistry from Southwest Texas State University.

4. I have reviewed the Office Action dated December 20, 2004, the above captioned patent application, the amended claims, and am familiar with the technology and steps described in the amended claims.

5. I understand that the Patent and Trademark Office Examiner in charge of assessing the patentability of the referenced patent application has rejected claim 22 of the application on the grounds that the terms “small molecule” and “synthetic molecule” have no definite meaning.

6. I am therefore providing the present Declaration to demonstrate that those of skill in fields of protein engineering and molecular biology understand the definition of term “small molecule” and “synthetic molecule” as they are used in the specification and claim 22.

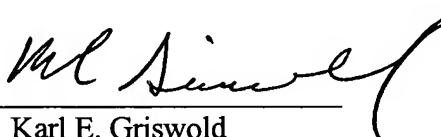
7. The term “small molecule” is in common use in the fields of protein engineering and molecular biology. A researcher of ordinary skill in these fields would understand that the term “small molecule” describes a low molecular weight molecule that is not based on repeating monomeric units. This definition is accepted in the art and well known. For example, a search in PubMed, a database of relevant scientific literature, revealed 788 references in which the words “small molecule” appear in the title alone (Appendix A). This evidences that skilled researchers fully understand the meaning of the term “small molecule.”

8. The term “synthetic molecule” is also common use in the fields of protein engineering and molecular biology. A researcher of ordinary skill in these fields would understand that the term “synthetic molecule” describes a molecule made through the actions of chemicals or biochemicals, as opposed to a molecule that is isolated from the natural world. This definition is accepted in the art and well known. For example, the relevant definition of the term “synthetic” from the online version of the Merriam-Webster online dictionary (<http://www.m-w.com/dictionary.htm>) is given as “produced artificially” (Appendix B). This evidences that meaning of the term “synthetic molecule” is well known to those of skill in the art.

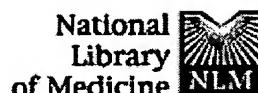
9. Based upon my skill and training in the areas of protein engineering and molecular biology, I therefore conclude that that a researcher of ordinary skill in these fields fully understands the definition of the terms “small molecule” and “synthetic molecule” as they are used in the specification and claims.

10. I hereby declare that all statements made herein of my knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

3/4/05
Date


Karl E. Griswold

APPENDIX A



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Search **PubMed**

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Field: Title

All: 788 Review: 132

Items 1 - 20 of 788

of 40 Next

1: [Ray SS, Nowak RJ, Brown RH Jr, Lansbury PT Jr.](#) Related Articles, Links

Small-molecule-mediated stabilization of familial amyotrophic lateral sclerosis-linked superoxide dismutase mutants against unfolding and aggregation. *Proc Natl Acad Sci U S A.* 2005 Feb 28; [Epub ahead of print] PMID: 15738401 [PubMed - as supplied by publisher]

2: [Selwood T, Smolensky H, McCaslin DR, Schechter NM.](#) Related Articles, Links

The Interaction of Human Tryptase-beta with Small Molecule Inhibitors Provides New Insights into the Unusual Functional Instability and Quaternary Structure of the Protease. *Biochemistry.* 2005 Mar 8;44(9):3580-90. PMID: 15736967 [PubMed - in process]

3: [Yau CY, Wheeler JJ, Sutton KL, Hedley DW.](#) Related Articles, Links

Inhibition of integrin-linked kinase by a selective small molecule inhibitor, QLT0254, inhibits the PI3K/PKB/mTOR, Stat3, and FKHR pathways and tumor growth, and enhances gemcitabine-induced apoptosis in human orthotopic primary pancreatic cancer xenografts. *Cancer Res.* 2005 Feb 15;65(4):1497-504. PMID: 15735038 [PubMed - in process]

4: [Buskirk AR, Liu DR.](#) Related Articles, Links

Creating small-molecule-dependent switches to modulate biological functions. *Chem Biol.* 2005 Feb;12(2):151-61. PMID: 15734643 [PubMed - in process]

5: [Berkson RG, Hollick JJ, Westwood NJ, Woods JA, Lane DP, Lain S.](#) Related Articles, Links

Pilot screening programme for small molecule activators of p53. *Int J Cancer.* 2005 Feb 23; [Epub ahead of print] PMID: 15729694 [PubMed - as supplied by publisher]

6: [Toenjes KA, Munsee SM, Ibrahim AS, Jeffrey R, Edwards JE Jr, Johnson DL.](#) Related Articles, Links

Small-Molecule Inhibitors of the Budded-to-Hyphal-Form Transition in the Pathogenic Yeast *Candida albicans*. *Antimicrob Agents Chemother.* 2005 Mar;49(3):963-72. PMID: 15728890 [PubMed - in process]

7: [Liu J, Wu X, Mitchell B, Kintner C, Ding S, Schultz PG.](#) Related Articles, Links

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APPENDIX B

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5 entries found for **synthetic**.
To select an entry, click on it.

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synthetic[2,noun]
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synthetic geometry
synthetic resin

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Main Entry: **1syn·thet·ic** [🔊](#)
Pronunciation: sin-'**the-tik**

Function: *adjective*

Etymology: Greek *synthetikos* of composition, component, from *syntithenai* to put together

1 : relating to or involving **synthesis** : not analytic
2 : attributing to a subject something determined by observation rather than analysis of the nature of the subject and not resulting in self-contradiction if negated -- compare **ANALYTIC**

3 : characterized by frequent and systematic use of inflected forms to express grammatical relationships

4 a (1) : of, relating to, or produced by chemical or biochemical **synthesis**; *especially* : produced artificially <*synthetic drugs*> <*synthetic silk*> (2) : of or relating to a synfuel **b** : devised, arranged, or fabricated for special situations to imitate or replace usual realities **c** :

FACTITIOUS, BOGUS

- **syn·thet·i·cal·ly** [🔊](#) /-ti-k(ə-)lē/ *adverb*

For [More Information on "synthetic" go to Britannica.com](#)

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